UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND
POLLUTION
PREVENTION

MEMORANDUM

Date: March 30, 2012

Subject: Efficacy Review for PERACLEAN® 5 (Peroxyacetic Acid Solution;
EPA Reg. No. 54289-3;
DP Barcode: 397438

From: Lorilyn M. Montford LM 4/11/12
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Tajah Blackburn, Team Leader
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4/11/12

To: Marshall Swindell PM33/ Karen Leavy
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Evonik Degussa Corporation
299 Jefferson Road,
Parsippany, NJ 07054

Formulation from the Label:

Active Ingredient(s)	% by wt.
Hydrogen Peroxide	26.5%
Peroxyacetic Acid	4.9%
Other Ingredients	68.6%
Total	100.0%

I BACKGROUND

The product, PERACLEAN 5 (EPA Reg. No. 54289-3), is an EPA approved disinfectant (bactericide, fungicide) and sanitizer for use on hard, non-porous surfaces in commercial, industrial, food preparation, and animal care environments. The applicant requested to amend the registration of this product to add a foaming agent for food and non-food contact sanitization. The label states that the product is effective as a sanitizer in water of up to 400 ppm hardness as $CaCO_3$. According to the registrant letter (dated November 14, 2011), "Evonik Degussa would like to add the use of a foaming agent." The study was conducted at MICROBIOTEST Labs, located at 105 Carpenter Drive in Sterling, VA 20164.

This data package contained a letter from the applicant to EPA (dated November 14, 2011), one study (MRID 486918-01), Statement of No Data Confidentiality Claims, and the proposed label.

II USE DIRECTIONS

The product is designed for sanitizing hard, non-porous surfaces, including: equipment, pipelines, tanks, vats, fillers, evaporators, and pasteurizers. The proposed label indicates that the product may be used on hard, non-porous surfaces, including: glass, glazed porcelain, linoleum, plastic (e.g., polyethylene, polypropylene), stainless steel, and vinyl. Directions on the proposed label provide the following information regarding preparation and use of the product as a sanitizing rinse on food contact surfaces: Prior to sanitizing, remove gross food particles. Wash with a detergent solution, followed by a potable water rinse. Prepare a use solution by adding 1.0 to 1.5 ounces of the product and 5 gallons of water (a 1:427 to 1:640 dilution). For treating against *Pseudomonas aeruginosa*, prepare a use solution by adding 2.1 to 2.3 ounces of the product and 5 gallons of water (a 1:278 to 1:305 dilution). Use immersion, coarse spray, or circulation technique as appropriate to the equipment. All surfaces should be exposed to the sanitizing solution for at least 60 seconds or more if specified by the governing sanitary code. Drain thoroughly and allow to air dry. Do not rinse.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Sanitizing Rinses (For Previously Cleaned, Food Contact Surfaces; Confirmatory Data

There are cases where an applicant may request to make minor formulation changes. In this situation, the change in the formulation is relatively minor, i.e., changes in an inert ingredient. The label claims and directions for use are unchanged from those accepted for the registered formulation, and specific references to the supporting data developed for the original formulation are cited by the registrant. In this situation, confirmatory testing standards would apply. For sanitizing rinses for previously cleaned, food contact surfaces, 2 product samples, representing 2 different product lots, must be tested. Results must show a bacterial reduction of at least 99.999% in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and the percentage reduction over the control. Furthermore, according to information in the above AOAC test method itself, counts on number controls for the

product should fall between 75 and 125 x 10^6/mL for percent reductions to be considered valid. In addition, label directions for use, however, must state that a contact time of at least 1 minute is required for sanitization.

Supplemental Claims

On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 486918-01 "Germicidal and Detergent Sanitizing Action of Disinfectants," Test Organism: *Escherichia coli* (ATCC 11229), for PERACLEAN 5, by Kathryn D. Dormstetter. Study conducted at MICROBIOTEST. Study completion date – October 26, 2011. Laboratory Project Identification Number 529-109.

This study was conducted against *Escherichia coli* (ATCC 11229). Two lots (Lot Nos. 8251080201 and 8251092801) of the product, PERACLEAN 5, were tested. The laboratory report referenced the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. At least one of the product lots tested was at least 60 days old at the time of testing (Lot No. 8251092801 was at least 60 days old in this case). Three different use solutions were prepared for each lot by adding (0.15 mL, 0.18 mL and 0.32mL) of the product to 99 mL of 400±2.9% ppm AOAC synthetic hard water + 0.15 mL foaming agent. A culture of the challenge microorganism was prepared in accordance with the published AOAC method. Use solutions were not tested in the presence of a 5% organic soil load. Three replicates per concentration were tested for both product lots. A 99-mL aliquot of each use solution was transferred to a 250 mL Erlenmeyer flask and placed in a water bath at 26°C. One-mL bacterial suspension was added to each flask. One-mL aliquots of the bacterium-product mixture were transferred to tubes containing D/E Neutralizing Broth exactly 60 seconds after the addition of the bacterial suspension. Neutralizer tubes were mixed thoroughly and serially diluted in phosphate buffer dilution water. Selected aliquots were plated in tryptone glucose extract agar. All plates were incubated for 48±2 hours at 37±2°C. Following incubation, the colonies were counted. Controls included those for numbers count, sterility, neutralizer effectiveness, and confirmation of the challenge microorganism.

V RESULTS

MRID Number	Organism	Lot No.	Dilution	Average No. Surviving	Microbes Initially Present	Percent Reduction
				(CFU/carrier)		
60-Second Exposure Time						
486918-01	*Escherichia coli*	8251080201	85 ppm	1.5×10^3 1.3×10^3 1.1×10^3	8.6×10^7 1.2×10^8 1.2×10^7	99.999% 99.999% 99.999%
			100 ppm	$< 5.0 \times 10^0$ $< 5.0 \times 10^0$ $< 5.0 \times 10^0$	8.6×10^7 1.2×10^8 1.2×10^7	>99.999% >99.999% >99.999%
			180 ppm	$< 5.0 \times 10^0$ $< 5.0 \times 10^0$ $< 5.0 \times 10^0$	8.6×10^7 1.2×10^8 1.2×10^7	>99.999% >99.999% >99.999%
60-Second Exposure Time						
486918-01	*Escherichia coli*	8251092801	85 ppm	1.2×10^3 1.3×10^3 1.2×10^3	8.6×10^7 1.2×10^8 1.2×10^7	99.999 99.999 99.999
			100 ppm	$< 5.0 \times 10^0$ $< 5.0 \times 10^0$ $< 5.0 \times 10^0$	8.6×10^7 1.2×10^8 1.2×10^7	>99.999 >99.999 >99.999
			180 ppm	$< 5.0 \times 10^0$ $< 5.0 \times 10^0$ $< 5.0 \times 10^0$	8.6×10^7 1.2×10^8 1.2×10^7	>99.999 >99.999 >99.999

VI CONCLUSIONS

1. The submitted efficacy do not data support the use of the product, PERACLEAN 5, as a sanitizing rinse foam application against the following microorganisms on pre-cleaned, hard, non-porous, food contact surfaces in the presence of 400 ppm hard water for a 60-second contact time at the specified dilution:

Escherichia coli MRID # 48691801

Although bacterial reductions of at least 99.999 % over the parallel control were observed within 60 seconds, data must be generated at a 30 second contact time. The proposed label must however reflect a 60 minute contact time for food contact sanitization. At least one of the product lots tested was at least 60 days old at the time of testing. Sterility controls did not show growth. Furthermore, the actual tested concentration of the active ingredient, at the time of testing is absent. This information is necessary for comparison of the Confidential Statement of Formula, to the tested product, to the proposed label.

VII RECOMMENDATIONS

1. The proposed label claims are unacceptable regarding the use of the product, PERACLEAN 5, as a sanitizing rinse against *Escherichia coli* on pre-cleaned, hard, non-porous, food contact surfaces in the presence of 400 ppm hard water for a 1-minute contact time. Efficacy must be generated at the 30- second contact time.

2. The following revisions to the proposed label are required:

- Under the "Precautionary Statements" section of the proposed label, change "before eating, drinking, or using tobacco" to read "before eating, drinking, chewing gum, using tobacco, or using the toilet."

- Add ATCC numbers are required for all microorganisms in one of these locations,
  - on the data matrix;
  - the master label (as optional text) with the listing of the organisms claimed, or
  - as the final page of the master label (as optional text).

- Correct the spelling of "*Pseudomonas aeruginosa*."

- Change "*E. coli* 0157:H7" to "*E. coli* O157:H7."

- Change "*Salmonella choleraesuis*" to "*Salmonella enterica*"